

## **OBJECTION TO THE SPECIFICATION**

In the instant action, Applicant's attention was drawn to page 31 of the specification, which appeared to contain a clerical error with respect to SEQ ID NO: 4 and 6. Specifically, the sequence labeled SEQ ID NO: 4, was suggested to correspond with SEQ ID NO: 5, as provided in the originally filed sequence listing. As shown above, the specification is amended herein to correct this error and to conform the application to the original Sequence Listing. Accordingly, no new matter is being introduced by this amendment.

## **REJECTION OF CLAIMS UNDER 35 U.S.C. § 112, FIRST AND SECOND PARAGRAPHS**

In the instant action, the rejections of claims 1, 10, 14, 24, 25, 86, and 87 under 35 U.S.C. § 112, second paragraph were upheld for failing to particularly point out and distinctly claim the subject matter because the claim element "a mapping means for locating a predetermined location in the brain" was argued to lack any associated structure within the application. These claims, as well as claims 89-98, were also rejected under 35 U.S.C. § 112, first paragraph for failing to adequately describe any structural recitation for the claim element "a mapping means." Because of the overlapping arguments asserted, Applicants address both of these rejections simultaneously below.

Under 37 CFR 1.57(c)(3), the structure for a means-plus-function claim recitation may be incorporated by reference from a U.S. Patent or U.S. Patent Application Publication. In the previous reply, Applicants respectfully noted that the section of the application entitled "Devices" incorporated by reference a sufficient number of examples such that one of ordinary skill in the art could identify that a "mapping means" referred to one or more imaging systems known in the art. U.S. Application 09/864,646 was one such incorporated reference that provided specific structural details for such support. Paragraphs 0029-0032, in particular, were discussed as exemplifying multiple, non-limiting embodiments of a radiographic markers used in combination with multiple imaging systems (e.g. MRI, stereotactic technique, X-ray, fluoroscopy) to map and observe the path of a catheter tip as it is positioned within the brain. While these paragraphs do not expressly use the term "mapping means," as recited in the instant claims, one of ordinary skill in the art would readily appreciate that such structural embodiments

are clearly contemplated by this disclosure. Accordingly, Applicants respectfully assert that the instant application clearly discloses the appropriate structure.

The instant office action attempts to undercut this reference by overstating the requirements for incorporation by reference. As noted above, 37 CFR 1.57(c) provides that essential matter may be incorporated by reference from a U.S. Patent or U.S. Patent Application Publication. While it is true that the material incorporated must be identified with some particularity, the actual level of particularity is based on the standard of one reasonably skilled in the art. *Advanced Display Systems v. Kent State Univ.*, 212 F.3d 1272, 1280 (Fed. Cir. 2000). The standard does not require an incorporation by reference to be particular in every instance; rather, all that is necessary is for one of ordinary skill in the art to understand what material is being incorporated by the reference mentioned. *Id.* Indeed, this is all that is required in 37 CFR 1.57(c), which was enacted after the *Advanced Display Systems* decision.

Applicant respectfully asserts that the instant specification does just that. The instant specification expressly states that the “devices and systems” of U.S. Application 09/864,646 is the subject matter being incorporated by reference. One of ordinary skill in the art would appreciate that such “devices and systems” refer to the exemplified and preferred embodiments disclosed in the application (i.e. radiolabeled markers, catheters, and imaging systems used to assist in installation, etc.) This type of identifying language is not only consistent with the provisions of 37 CFR 1.57, but is also consistent with the particularity requirement of *Advanced Display Systems*. Accordingly, Applicants respectfully assert that the foregoing application effectively provides structure for the instant claims so as to traverse the instant rejections under 35 U.S.C. § 112, first and second paragraphs.

#### **NEW MATTER REJECTIONS UNDER 35 U.S.C. 112, FIRST PARAGRAPH**

Claims 1, 10, 14, 24, 25, 86, 87, and 89-98 were further rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter that was not described in the specification (i.e. for containing new matter). First, claims 1 and 90 were identified as including a catheter and radiographic marker, respectively, which included “a radiographic marker.” While the instant action acknowledged that a radiographic marker was disclosed U.S. Ser. No. 09/864,646, discussed above, it was, again, argued that this limitation was not identified in sufficient detail in the application to be considered fully supported. In conjunction with the reasoning above,

Applicant respectfully disagrees. The instant specification clearly identifies that U.S. Ser No. 09/864,646 was incorporated by reference only for the material related to its devices and associated systems. Accordingly, Applicant respectfully asserts that one of ordinary skill in the art would understand that such a limitation is incorporated by reference with particularity to satisfy the standard under 37 CFR 1.57(c) and that set forth in *Advanced Display Systems v. Kent State Univ.*, 212 F.3d 1272, 1280 (Fed. Cir. 2000).

Claim 1 was also rejected as containing new matter because the amended claim term “wherein said small interfering RNA hybridizes to a sequence identical to SEQ ID NO:1 within the ataxin-1 mRNA” into claim 1 was argued as not being supported by the instant specification. Specifically, it was argued that the antisense strand, because it contains a two base-pair overhang that does not correspond with the sense strand, would not hybridize to the full sequence of SEQ ID NO: 1. In response, Applicant respectfully asserts that the claim is being read with additional limitations not provided. As written, claim 1 recites an siRNA that hybridizes to a sequence identical to SEQ ID NO: 1. Nothing in the claim requires hybridization to the full sequence. Rather, all that is necessary is hybridization. As illustrated in Examples 1 and 2, this is exactly what was seen by siRNA AT0945 (i.e. SEQ ID NOS: 1 and 2). Thus, Applicants respectfully submit that this amendment was fully supported by at least the Examples section of the instant application.

Although Applicant disagrees with the foregoing rejection, in the spirit of furthering prosecution, Applicant amended claim 1 to clarify that that the siRNA sufficiently hybridizes to a sequence identical to SEQ ID NO: 1 within the ataxin-1 mRNA to inhibit ataxin-1 expression. Applicant respectfully submits that support for this amendment may, again, be found in the instant application at Examples 1 and 2 so as not to introduce new matter. This amendment clarifies that full hybridization is not necessary. All that is required is sufficient hybridization to inhibit mRNA translation.

Finally, claim 98 was further argued to contain new matter because the application did not provide a written description for a sense strand of siRNA that is at least 90% complementary to the antisense. Again, Applicant respectfully disagrees. The siRNA structure of AT0945 discloses an anti-sense strand in SEQ ID NO: 2, having 21 nucleotides. Exactly 90% of the nucleotides in the corresponding sense strand of SEQ ID NO: 1 are complementary. Under MPEP 2163, Applicant respectfully asserts that the disclosure of SEQ ID NO: 1 and 2, in and of

itself, sufficiently identifies relevant, identifying characteristics, to show the Applicant was in possession of the claimed genus. Nevertheless, in the interest of furthering prosecution of this case, Applicant canceled claim 98 without prejudice to Applicant's right to pursue this claim in a continuing or divisional application.

### CONCLUSION

In view of the remarks above, Applicant submits that the pending claims are valid and favorable reconsideration and allowance are earnestly solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that the Examiner telephone Applicant's attorney at (609) 844-3020 to discuss any additional rejections.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

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Respectfully submitted,

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